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655 15th Street, N.W.
Washington, DC 20005-5701
Tel: (202) 452-8444
Fax: (202) 429-4519
E-mail: fmi@fmi.org
Website: www.fmi.org

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

**Re: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0276; 68 Fed. Reg. 5378 (Feb. 3, 2003)**

Dear Sir or Madam:

The Food Marketing Institute welcomes this opportunity to comment on the Food and Drug Administration's (FDA's) proposed rule to implement Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act or the Act).[1/] FMI appreciates FDA's efforts to implement this important provision of the Act. We are especially pleased to see that FDA's proposed rule is consistent with several suggestions FMI made in the comments we submitted to FDA prior to the proposal's publication. While FMI is supportive of many provisions of the proposed rule, we believe that the agency's interpretation of the term "retail establishment" does not properly reflect the scope of the definition of this term as clarified by the legislative history. Specifically, FDA's regulations should specifically state that the term includes "attendant facilities," such as retail warehouses, as well as club stores.

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1/ FMI conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 60 countries.

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Moreover, we are concerned that certain provisions have the potential to be overly burdensome. FMI believes that minor modifications to the proposal would bring the final rule in line with Congressional intent and provide needed flexibility while allowing the agency to collect the information necessary to further the goals of the registration requirement. Our comments are outlined in detail below.

## I. "Other Retail Food Establishments" Definition Should Include "Attendant Facilities" (such as Warehouses) and Club Stores

Section 305 of the Bioterrorism Act requires all facilities that manufacture, process, pack or hold food to register with the agency, with exceptions for, among other entities, restaurants and "other retail food establishments." The legislative history explicitly states that the term "other retail food establishment" includes "facilities attendant to their operations, which are under the same ownership or management." 148 Cong. Rec. at H2858. FDA's proposal would expressly exempt retail facilities defined by the agency as "facilities that sell food products directly to consumers only."

FMI urges FDA to amend the proposed definition of retail food establishment in two important respects to bring the definition in line with the statutory definition as clarified by the legislative history. First, although FDA's proposal correctly acknowledges that central kitchens would be included in this definition, the Agency fails to recognize that distribution centers owned or managed by the retail establishment also constitute "facilities attendant to their operations." FMI asks FDA to clarify that the term "retail food establishments" includes all attendant facilities, such as distribution facilities.

Second, the agency states in the preamble that the "other retail food establishments" definition would include grocery and convenience stores, but not club stores. The legislative history, however, indicates that Congress intended to exempt club stores -- as retail food establishments -- from the requirement to register. Specifically, the legislative history defines "other retail food establishments" as facilities that store, prepare, package, serve or otherwise provide articles of food directly to the retail consumer for human consumption. 148 Cong. Rec. at H2726. Club stores clearly fall within this definition. Although club stores, on occasion, sell food to wholesalers and restaurants, nowhere in the legislative history does Congress restrict the definition of retail food establishments to those establishments that sell food *only* to retail consumers, as FDA proposes.

The Bioterrorism Act's registration provision is intended to provide FDA with a list of some of the facilities involved in the manufacturing, processing, packing, or holding of food for purposes of preparing for or responding to potential or actual threats of terrorism and other public health emergencies, but not all – Congress chose to expressly exempt restaurants as a class. In choosing to exempt other retail food establishments from the registration requirement, Congress presumably contemplated that

the agency would have sufficient information concerning retailers and restaurants due to their high visibility by virtue of direct sales to consumers. The same logic applies to club stores as retail establishments for which a large portion of their sales are directly to consumers. Accordingly, FMI urges the agency to refrain from unnecessarily limiting the scope of the retail establishment exemption in a manner that does not enhance food security and to clarify that club stores, like grocery stores, are exempt from the registration requirement.

## II. The Requirement To Submit Updates Should Be Limited

The Act provides that registrants must notify FDA "in a timely manner of changes" to the information contained in the registration. FDA's proposed implementation of this requirement would mandate updates within thirty days of a change in any of the information provided in the registration. Such a requirement would be overly burdensome, with companies having to submit updates on a regular basis for minor changes in product lines, personnel, and other information.

FDA has stated that a primary function of the registration requirement is to allow the agency to communicate rapidly with registered facilities in the event of a potential or actual terrorist threat to food or other public health emergency. FMI suggests, therefore, that FDA limit any requirement for a 30-day update to changes in emergency contact information. FMI further recommends that the agency expand the registration form to provide registrants with the option of providing an alternative emergency contact to serve as "back-up" in the event that the primary contact is not available. The agency could require updates to emergency contact information only if the information provided for both contacts has changed.

If the agency were to require updates to be submitted for any additional information provided in the registration, it should be limited to significant changes such as changes in the facility's ownership or substantial differences in the products distributed, manufactured, handled or processed at the facility. As suggested in the comments FMI submitted to FDA prior to the proposal's publication, updates to such information could be made every June or December, as required for changes to drug listings if a new drug is manufactured or discontinued in the facility during the previous six months. See 21 C.F.R., Subpart C, e.g., § 207.30. A minor change to registration information, such as a new area code, could be made at the same time, but should not trigger the update requirement in and of itself.

## III. Temporary Storage Facilities Should be Exempt from Registration

FMI encourages the agency to clarify that temporary storage facilities (e.g., leased public storage) that hold food for short periods of time are not "facilities" for registration purposes. The grocery industry utilizes public storage facilities on occasion to store seasonal merchandise for typically less than a month. Because such facilities

"hold" or store food products, they may be required to register as food facilities under the proposal. If the owner, operator, or agent-in-charge of temporary storage spaces used to hold food were required to register, they would have to submit and cancel registrations all within less than two months in most instances. Such a requirement would be unduly burdensome on retailers and FDA, providing unnecessary paperwork for the agency to process on a regular basis, while doing little to improve food security. Accordingly, the agency should revise the definition of "facility" or "hold" to indicate that structures used to store food temporarily (i.e., less than one month) are not required to register under the proposal.

## IV. General Food Categories Should Not be Required

Section 415(a)(2) of the Act allows the Secretary to require registrations to include the "general food category" of any food manufactured, processed, packed, or held at such facility "when determined necessary by the Secretary through guidance." Section 415 (a)(2). Section 170.3(n) identifies 43 general food categories that the Agency established to group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients. FDA stated that individual food products would be included within the categories in accordance with detailed classification lists contained in a 1972 National Academy of Sciences report on the use of "generally recognized as safe" (or GRAS) substances in food. Section 170.3 pre-dates the 1977 re-codification of FDA's regulations.

In the preamble the Agency explains the basis for their decision to require the submission of general food categories. Although we do not necessarily agree with FDA's decision in this regard, we are pleased that the Agency agreed with our request in the comments submitted on the statute to provide a mechanism for those facilities at which all general food categories are relevant to respond. Specifically, FDA's draft registration form allows facilities that handle all general food categories to state "Most/All Human Food Product Categories" in lieu of identifying individual food categories on the registration. A situation in which a facility that normally carries all food categories has run out of products in a specific food category, but intends to re-stock the items, should not require amendment of the registration or subject the facility to penalties.

## V. Registration Process

FMI supports FDA's decision to allow a company's headquarters to submit registration information on behalf of all of the facilities it owns, operates, or for which it acts as an agent. FDA could ease significantly the burden of submitting registration information for each facility owned by a company by allowing the transmission of electronic data files. This would allow a company operating from its headquarters to submit a single file encompassing required registration information for all facilities it must register, streamlining the administrative burden associated with the new regulation.

**VI. Protection of Information**

Section 415(a)(4) of the Act requires FDA to develop and maintain an up-to-date list of registered facilities, but protects the list, underlying registration documents, and any identifying derivative information from public disclosure. FDA's implementing regulations, as well as the Agency's public information regulations in 21 C.F.R., Part 20, should reflect the protected status of these records and FDA has added proposed Section 1.243 to reflect this provision of the Act.

However, we are concerned about the potential accessibility of the information if FDA shares it with the states. We urge the Agency to clarify in the final rule that the registration information that cannot be disclosed under the Freedom of Information Act will not be disclosed to state agencies or, if it will, to specify the mechanisms that the Agency will implement to ensure that the information that Congress required to be protected will not otherwise be subject to disclosure under FOIA.

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We hope that you will consider the foregoing recommendations as you develop the final regulation to implement the registration requirements of Section 305 of the Bioterrorism Act. If we may provide any additional information in this regard, or if we may be of assistance in any other way, please do not hesitate to contact us.

Sincerely,

Deborah R. White
Associate General Counsel,
Regulatory Affairs

FOOD MARKETING INSTITUTE

# TRANSMITTAL FAX

Registration Comments

**TO:** FDA Dockets : 02N-0276

DATE: April 4, 2003

COMPANY: _____

DEPT: _____

PHONE: _____

FAX: 301/827-6870

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**FROM:** Deborah White

DEPT: Legal

PHONE: 202/220-0014

FAX: _____

**Supermarket Industry Convention and Educational Exposition**
May 4 - 6, 2003
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**Public Policy Conference**
October 15-17, 2003
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**ADDITIONAL INFO/NOTES:**

**FOOD MARKETING INSTITUTE**
655 15th STREET, NW • WASHINGTON, DC 20005 • TEL. 202/452-8444